Medtronic

# AEX™ Generator Service Guide

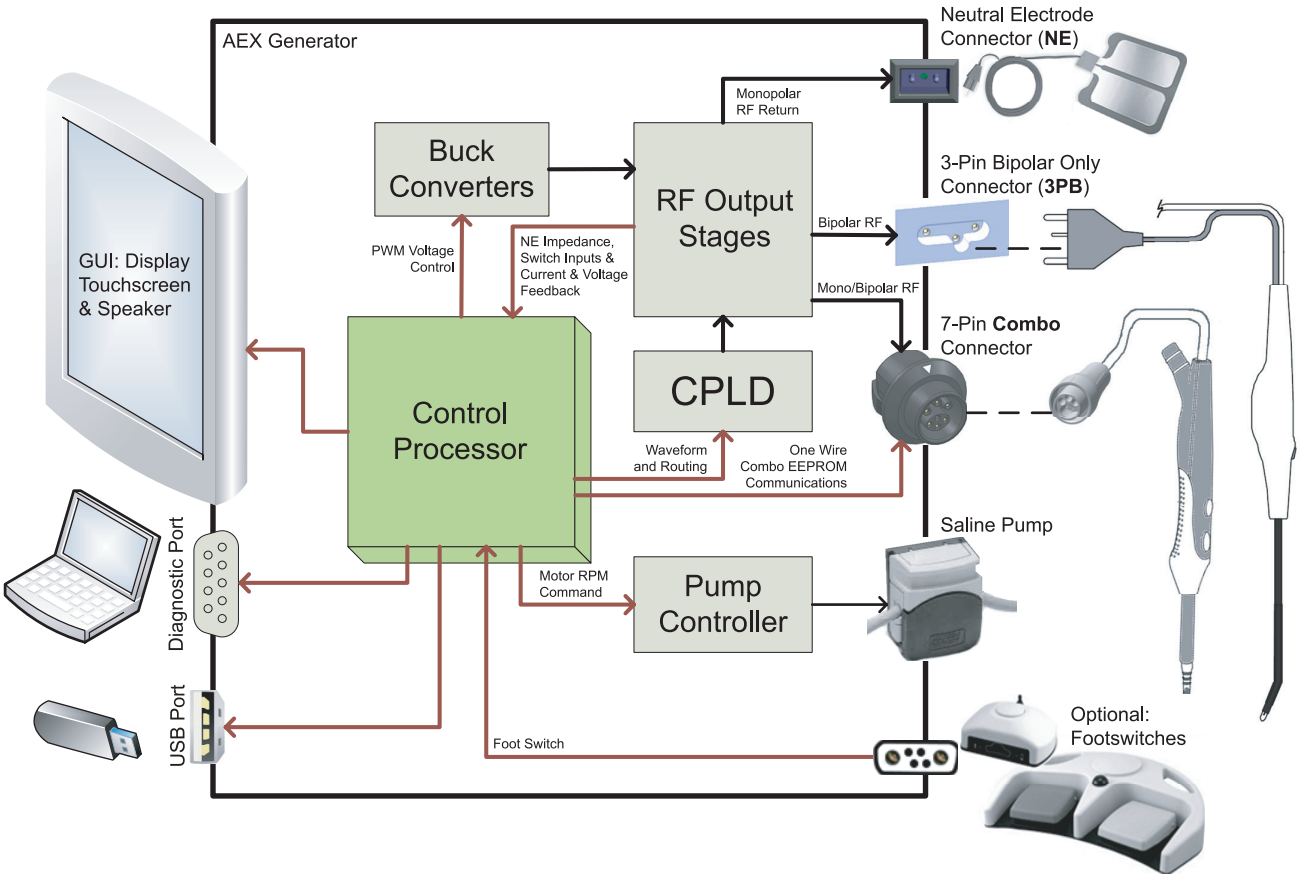
**Intended Use of this Document**

▲ **WARNING:** The information contained in this document is intended for the use of qualified personnel only. Biomedical technicians (e.g., ICC Certified Biomedical Equipment Technician [BMET]) or similar personnel performing the steps outlined here shall be fully familiar with all documentation on the functions, operations, warnings and components of the AEX™ Generator. Serious injury can result if the activities described in this document are attempted by unqualified persons.

## AEX™ Generator Service Procedure

The AEX™ Generator provides radio frequency (RF) energy to a disposable electrosurgical device. This combined system is used to perform electrosurgery. The generator is capable of delivering multiple CUT, COAG and Transcollation™ modes at various power levels when connected to a disposable device. The 7-pin disposable devices have a memory chip with predetermined set points, see device user manuals for specific information. This chip specifies the output power for each set point. The generator reads this 7-pin device memory chip to deliver RF power. The 3-pin disposable devices do not have a memory chip.

**Figure 1-1.** System Component Interface Diagram




## Equipment Required

The following equipment will be required to complete the output power accuracy testing:

- AEX™ Generator
- A neutral electrode (return pad) connector with the pad cut off and the two leads shorted together
- Disposable device
  - 3-pin: Aquamantys™ 6.0, MBS
  - 7-pin: PlasmaBlade™ 3.0S or 4.0
- Electrosurgical analyzer (ESA) (capable of measuring RF output at 469 KHz)
- Stopwatch
- Container to collect fluid
- Test leads with alligator clips
- Safety tester for medical units as per IEC #60601

## Required Annual Inspections

1. Visually inspect the AEX™ Generator for physical damage. Report damage to Medtronic Advanced Energy or your biomedical department. Do not use the Generator if it is damaged.
2. Visually inspect the power cord and plug for physical damage. Replace the cord if the insulation has been breached. Do not use the Generator if the cord or plug has been damaged and has not yet been replaced.
3. Inspect the tightness of the power plug. If it is loose, it must be replaced with Medtronic Advanced Energy approved components.
4. Inspect the mating, cleanliness, and absence of damage to the patient connectors. Do not use the AEX™ Generator if the connectors are damaged.
5. Inspect for accumulation of lint or debris within the AEX™ Generator or fan vents. Do not use the AEX™ Generator if lint or debris has accumulated and has not been cleared.

## Maintenance and Repair

This section contains information about routine maintenance.

▲ **WARNING:** Do not modify this equipment. Only authorized Medtronic Advanced Energy service technicians may make modifications to the AEX™ Generator.

## Routine Maintenance

#### Recommended Periodic Functional Verification

The AEX™ Generator should be periodically checked for functionality and performance according to your hospital's equipment servicing guidelines. Medtronic Advanced Energy recommends that the unit's calibration be verified and a safety check be performed by a qualified biomedical technician on an annual basis as outlined below. Reference the ESA Manual for specific instructions for safety tests.

#### Recommended Functional Verification Procedure

The verification and functional check should include:

- Protective earth conductor test
- Earth leakage current measurement
- Housing leakage current measurement
- Output power accuracy verification
- Peristaltic pump test (function, flow rate accuracy)
- Test of visual indicators
- Test of alarm tone and volume control function
- Power cord inspection (for damage)
- Fuse check

#### Leakage currents and protective earth conductor test

The following connections should be established according to the safety tester's instructions:

- Male end of AEX™ Generator's power cord into the safety tester mains socket.
- The AEX™ equipotential bonding terminal (see AEX™ Operator's Manual page 2-4, Figure 2-3 for location) to safety tester respective terminal.

Perform leakage and PE conductor tests per the safety tester instructions. The following limits must be complied with in accordance with IEC #60601 (Class I, Type CF device):

**Table 1**. Leakage Current and PE Conductor Limits

| Measured Characteristic | Maximum Value |
|---|---|
| PE conductor impedance | 0.2 Ω |
| Earth leakage current, normal condition | 500 µA |
| Earth leakage current, single fault condition | 1000 µA |
| Housing leakage current, normal condition | 100 µA |
| Housing leakage current, single fault condition | 500 µA |

## RF Output Power Accuracy Verification

▲ **WARNING:** Load resistors used to test the output of the AEX™ Generator will become extremely hot. Use extreme caution to avoid any contact. All load resistors must be properly mounted and isolated from any flammable materials.

◆ **PRECAUTION:** The ESA must have a current rating of at least 2.5 Arms. Do not test the AEX™ Generator with a load of less than 50 ohms on the output – RF currents in excess of 2.5 amps rms will occur.

It is preferable that these measurements be performed using an electrosurgical analyzer which is intended for this purpose, however it is possible to perform this testing manually if required. The manual method is achieved with a high frequency current sensing coil (i.e.: Pearson Electronics model #4100), an Oscilloscope or Wide Band RMS voltmeter, and non-inductive load resistors of appropriate resistive values and power ratings. The delivered power will be calculated as I2R. Contact a Medtronic Advanced Energy Customer Service representative at +1 866 777 9400 for further assistance.

### Power Output Tests - 3 Pin Device (Aquamantys™ 6.0, MBS)

The RF output should be tested at 20 watt, 110 watt, and 220 watt settings with the output loaded at 100 ohms. The measured RF output power should be equal to the set power ±20%. The object is to compare the measured output power for rated load to the output power vs. resistance curve in the Technical Specifications section of the operator's manual, applying a tolerance of ±20%. Contact a Medtronic Advanced Energy Customer Service representative at +1 866 777 9400 for further assistance.

● **NOTE:** Prime must be performed before 3-pin device can activate, prime can be performed without tubing inserted into pump.

**Table 2.** AEX™ Power Output Specs for 3-pin device

| Setting | Power (Watts) | Impedance (Ohms) | Tolerance |
|---|---|---|---|
| 20 W | 20 W | 100 | +/- 20% |
| 110 W | 110 W | 100 | +/- 20% |
| 220 W | 220 W | 100 | +/- 20% |

### Power Output Tests - 7 Pin Device (PlasmaBlade™ 3.0S or 4.0)

The Power Output Tests provide a means for the user to verify the accuracy of the RF energy output. The procedure to measure output power is as follows:

1. Connect the disposable device to the generator under test.
2. Connect the tip of the 7-pin device (metal needs to be exposed) to the ESA leads using an alligator clip.
3. Connect the shorted leads of the neutral electrode to the ESA leads using an alligator clip.
4. Set the load on the ESA to the value indicated on the appropriate table, (Table 2 for 3-pin and Table 3 for 7-pin). Refer to the ESA's Instruction manual for set up instructions.
5. Power on the generator and adjust to the appropriate set point per the table.
6. Press the button (yellow for CUT and blue for COAG) on the 7-pin device to activate RF. Measure the output power on the ESA. Refer to Tables 2 and 3 for accuracy of measured power depending on the type of device connected.
7. **This should be repeated for all the values highlighted in *Bold Italics* at a minimum**. Other values are presented for additional testing.

   Contact a Medtronic Advanced Energy Customer Service representative at +1 866 777 9400 for further assistance.

**Table 3.** AEX™ Power Output Specs for 7-pin device

| Setting | Mode | Power (Watts) | Impedance (Ohms) | Tolerance |
|---|---|---|---|---|
| Cut 1 | Low Cut | *0.66 | 100 | *None Prescribed |
| Cut 2 | Low Cut | *2 | 100 | *None Prescribed |
| Cut 3 | Low Cut | 5 | 100 | +/- 20% |
| Cut 4 | Low Cut | 10 | 100 | +/- 20% |
| Cut 5 | Low Cut | 19 | 100 | +/- 20% |
| Cut 6 | Medium Cut | 21 | 500 | +/- 20% |
| Cut 7 | Medium Cut | 37 | 500 | +/- 20% |
| ***Cut 8*** | ***Medium Cut*** | ***53*** | ***500*** | ***+/- 20%*** |
| Cut 9 | High Cut (Blend 1) | 24 | 500 | +/- 20% |
| ***Cut 10*** | ***High Cut (Blend 2)*** | ***49*** | ***500*** | ***+/- 20%*** |
| Coag 1 | Low Coag | 16 | 500 | +/- 20% |
| Coag 2 | Low Coag | 21 | 500 | +/- 20% |
| Coag 3 | Low Coag | 27 | 500 | +/- 20% |
| Coag 4 | Low Coag | 32 | 500 | +/- 20% |
| ***Coag 5*** | ***Low Coag*** | ***37*** | ***500*** | ***+/- 20%*** |
| Coag 6 | High Coag | 29 | 1000 | +/- 20% |
| Coag 7 | High Coag | 33 | 1000 | +/- 20% |
| ***Coag 8*** | ***High Coag*** | ***38*** | ***1000*** | ***+/- 20%*** |
| Coag 9 | High Coag | 42 | 1000 | +/- 20% |
| Coag 10 | High Coag | 47 | 1000 | +/- 20% |

**Flow Rate Test**

- **NOTE:** The use of saline or water and a 3-pin device is required to verify flow action and pump function.

1. Plug the 3-pin disposable device into the front panel connector of the AEX™ Generator.
2. Load the pump tubing segment of the disposable device into the pump head and close the pump head.
3. Prime the system until saline flows from the electrodes of the hand held device.
4. Use fluid measuring containers to collect fluid, measured in cc/minute.
5. Use a stop watch to time flow for 1 minute for the following settings:
   - 20W low flow (.5 to 3.5 cc/min)
   - 100W medium flow (9.6 - 16 cc/min)
   - 200W high flow (23.6 - 39.3 cc/min)

Contact a Medtronic Advanced Energy Customer Service representative at +1 866 777 9400 for further assistance.

## Cleaning

▲ **WARNING:** ***Electric shock hazard.*** Always unplug the Generator from the wall outlet prior to cleaning.

The Generator is not sterilizable.

Clean the front display, cover, and cord with a mild detergent or mild disinfecting solution and damp cloth.

It is recommended that non-flammable agents be used for cleaning and disinfection whenever possible. If flammable agents are used for cleaning, disinfecting, or as solvents, they should be allowed to evaporate before surgery.

◆ **PRECAUTION:** Do not allow fluids to enter the chassis. Do not use alcohol, caustic, corrosive, or abrasive materials on the front display, cover, and cord, as they may cause damage to the equipment. Medtronic Advanced Energy recommends following hospital procedures for cleaning the outside of the Generator after each patient.

Refer to the **Footswitch Operator's Manual** for detailed cleaning instructions for the footswitch and receiver. Contact a Medtronic Advanced Energy Customer Service representative at +1 866 777 9400 for further assistance.

## Responsibility of the Manufacturer

Medtronic Advanced Energy is responsible for the safety, reliability, and performance of the AEX™ Generator only under the following circumstances:

- Installation and setup procedures in this service guide and the operator's manual are followed.
- Assembly operation, readjustments, modifications, or repairs are carried out by persons authorized by Medtronic Advanced Energy.
- The AEX™ Generator is connected to electrical wiring which complies with local codes and regulatory requirements.
- The equipment is used in accordance with the AEX™ Generator instructions for use.

For warranty information, refer to the AEX™ Generator Operator's Manual.

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**Rx Only:** Federal Law (USA) restricts these devices to sale by or on the order of a physician.

For a listing of indications, contraindications, precautions, and warnings, please refer to the Instructions For Use (IFU) that accompany the Medtronic Advanced Energy disposable devices and/or the AEX™ Generator Operator's Manual.

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